

REMARKS

Claims 17-25 and 29, as amended, and new claims 31-33, are pending for the Examiner's consideration. Allowed claims 1-11 and 26-28 have been canceled and filed in a new co-pending application as of December 8, 2005 to claim priority to this application. Claim 29 has been amended to more clearly and distinctly recite the invention, whereby the channel is present and extends substantially along the length of each arm of the umbilical cord clamp, and that each channel is open only at the free end of each arm. New claim 31 recites a preferred width of each channel with respect to each arm (*See* original claim 14). New claim 32 recites that each arm has a channel (*See, e.g.,* Specification at page 9, lines 10-11). New claim 33 recites that the channel is open only at the free end portion of each arm (*See, e.g.,* Specification at page 9, lines 29-30). Applicant has canceled the allowed claims to reduce the issues for allowance, or for eventual appeal. No new matter has been added and no new issues raised by this Amendment, such that the claims should be entered at this time.

Initially, claim 29 was rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,938,666 to Reynolds et al. ("Reynolds") on page 2 of the Office Action. The Office Action states that Reynolds identically discloses each and every feature recited by claims 26-30. In particular, the Office Action alleges a channel 21,22 that extends substantially along the length of at least one arm and is open at the free end portion.

Claim 29 recites that the depth of the channel increases toward each open end, which advantageously facilitates removal of fluid in a single direction away from the umbilical cord. Reynolds fails to disclose or even suggest this feature. Indeed, Reynolds does not even acknowledge that it would be desirable to increase the channel in one direction or the other. On the contrary, Reynolds actually *teaches away* from the claimed invention by disclosing that the webs (21,22) are *parallel to and preferably co-planar* to the root plane of opposite interior serrated surfaces, so blood is forced out of the vessels and artery of the cord in *opposite directions* (Col. 4, lines 38-42). This teaches that blood is removed out either end of the clamp arms and that the channels do not have varying depth but the same depth, *i.e.,* they are co-planar (*see, e.g.,* Col. 3, lines 63-65; Col. 4, line 65 to Col. 5, line 6). Thus, Reynolds clearly fails to disclose or remotely suggest an umbilical cord clamp structure where the channel depth is increased toward each open end.

Moreover, new dependent claim 33 further recites that each channel is open only at the free end of each arm. Reynolds fails to disclose this recited feature, and actually teaches the opposite by disclosing that the channel webs are parallel and preferably co-planar. Thus, Reynolds

fails to disclose or remotely suggest, particularly when there is only a single open end, each and every recited feature of claims 29 and 31-33, such that the rejection of claim 29 under 35 U.S.C. § 102(b) should be reconsidered and withdrawn.

Claims 17-25 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,006,830 to Merritt ("Merritt") in view of U.S. Patent No. 6,132,447 to Dorsey ("Dorsey") on page 3 of the Office Action. The Office Action states Merritt provides all the features of claim 17 except the gender-identifying color associated with a portion of the clamp. The Office Action then relies on Dorsey in a "similar art" to allegedly evidence use of a device "to provide umbilical devices with gender-identifying color coding" for readily recognizable indicia associated with newborns, and that this would have been recognized as being readily adapted for umbilical cord severing.

In discussing the patentable distinctions of the claimed invention over the cited references, Applicant refers the Patent Office to the Small Declaration made of record when filed on February 11, 2005. Merritt discloses an umbilical cord clamp that contains particular types of *unique* identification marks including a serial code, bar code, color code, or letter combination, each of which has a different *distinctive* mark thereon (Col. 4, lines 10-24). Merritt fails to disclose the inclusion of a color, including shades thereof, to provide identification means comprising a gender-identifying color to facilitate identification of the gender of a baby, as presently recited. At best, it discloses a *color code* to prevent unauthorized removal of a newborn from a pre-defined area. Thus, Merritt requires a color code, which is presumably at least a pattern of multiple colors, *e.g.*, a multi-colored bar code, to provide identification for its stated purpose of preventing unauthorized removal of a baby from a security zone (*See, e.g.*, Small Declaration at ¶ 6).

On the contrary, Dorsey is directed to a completely different article--blue or pink labeled scissors used to cut an umbilical cord, rather than a clamp to hold the remaining portion of the cord. Dorsey's scissors do not remain with the newborn or in association with the umbilical cord, but instead are separately packaged and provided in a nice display for the parents. At best, Dorsey provides a novelty toy to new parents, or perhaps a souvenir of the baby's birth in the hospital (*See, e.g.*, Small Declaration at ¶ 7). Dorsey does not, however, teach to provide a gender-identifying means that is clamped onto the newborn's umbilical cord or otherwise associated with a portion of the clamp to facilitate identification of the gender of the baby (*See, e.g.*, . While Dorsey is simply a reminder to anyone seeing it that the possessor has a *child* is of a particular gender, claim 17 recites that the gender-identifying means facilitates identification of the gender of a baby while the clamp remains on the baby, i.e., the gender-identifying means remains with the baby until the umbilical cord stump and/or clamp fall off or are physically removed. This natural falling off of

the cord with clamp on it typically takes 2 to 4 weeks for a typical baby, which is significantly and surprisingly longer than the momentary contact Dorsey teaches while the cord is cut. Dorsey's colored scissors are never on the baby, as presently recited, as they are momentarily used to cut the umbilical cord (*See, e.g.*, Small Declaration at ¶ 7).

Aside from a hindsight rejection, it is not seen that the references themselves provide sufficient motivation that one of ordinary skill in the art would have combined them, much less arrived at the claimed article and methods. Merritt discloses an identification system to deter the unauthorized removal of a newborn from a defined area, while Dorsey provides blue or pink scissors to cut a baby's umbilical cord. Aside from both generally relating to the birthing experience, the references themselves contain absolutely no motivation whatsoever to suggest to one of ordinary skill in the art that they could have been combined in some way (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

It is settled law that bald assertion is not sufficient to maintain this rejection, as the Federal Circuit requires that a teaching or motivation to combine be present in the cited art of record. In the obviousness context, a motivation must have existed for one of ordinary skill in the art to combine the references--and this lack of such a motivation in the art of record demonstrates the patentability of the claims over the cited references, or at the very least demonstrates the lack of a *prima facie* case of obviousness by the Patent Office.¹ Absent the motivation to combine a gender-identifying color on a pair of novelty scissors, with a cutting function, with a color code for security purposes on an umbilical cord clamp, Merritt and Dorsey failed to provide those of ordinary skill in the art with any motivation to select the gender-identifying color of Dorsey in hindsight and apply it to the uniquely coded article of Merritt (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

For example, the final Office Action states that Merritt teaches a clamp that remains on the baby, *i.e.*, on the cord stump of the baby, and Applicant readily acknowledges this. Dorsey and Merritt, however, still fail to provide a motivation to for one of ordinary skill in the art to provide a gender-identifying color from scissors onto a clamp to provide a gender-identifying function by remaining with the baby for a period of time (*See, e.g.*, Small Declaration at ¶¶ 7-8).

¹ *In re Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir., 2002) (finding that the Board of Patent Appeals and Interferences improperly relied upon common knowledge and common sense of person of ordinary skill in art to find invention of patent application obvious over combination of two prior art references, since factual question of motivation to select and combine references could not be resolved on subjective belief and unknown authority).

Dorsey's separate scissors, with a cutting function, simply do not provide a motivation to keep the presently recited gender-identifying color with the baby, or even to use its colors to identify the gender of the baby, as Dorsey teaches to place the scissors in a frame or package immediately after cutting the cord (*Id.*). As such, even the combination fails to teach the presently recited clamp with gender-identifying color (*Id.*).

In fact, Dorsey *teaches away* from Merritt, because Merritt discloses that every clamp should have a different distinctive identification mark thereon. Dorsey, however, teaches use of the pink and blue coatings on its scissors to identify gender (Col. 2, lines 13-27) of an entire class of people rather than a unique security identifier. Dorsey thus teaches a gender-identifying color on a pair of scissors that is not associated with a baby and that is not a sufficient universe of colors to create a security code, *e.g.*, a "color code," or to uniquely and distinctly identify every newborn in a given hospital or health care facility as required by the fundamental purpose of Merritt's teachings (*See, e.g.*, Small Declaration at ¶¶ 6-8). While Dorsey does teach other colors like green and yellow, which are used when the baby's gender is undetermined, this does not provide the missing motivation to combine the references.

Moreover, Dorsey teaches that the scissors are *separated from the baby* to be cleaned after severing the umbilical cord from the mother, further processed (labeled with birth data), framed or packaged, and presented to the child's parents (*See, e.g.*, FIG. 3 and Small Declaration at ¶ 8). On the contrary, it is essential for Merritt's clamp to *remain on the baby* to provide its inventive security function. Merritt's clamp, to function as intended, is processed before application to the baby for maximum security, while Dorsey's scissors are processed after cutting and do not remain with the baby. Indeed, Dorsey's scissors are not intended to function as a gender-identifying means, because they are *provided to the child's parents* rather than remaining on or even necessarily near the baby (*See, e.g.*, Small Declaration at ¶ 7). This also teaches away from placing a clamp on a baby, as taught by Merritt. In view of these significantly different purposes and functions, one of ordinary skill in the art would not have been motivated to combine selected features from Dorsey and Merritt in the absence of guidance from the present specification regarding the presently recited surprising and unexpected invention (*See, e.g.*, Small Declaration at ¶¶ 8 and 12).

Even if a motivation to combine Dorsey and Merritt existed, which it does not, and a reasonable expectation of success in doing so existed, which it clearly does not, evidence of the secondary factors of obviousness need to be considered in an obviousness determination. One important secondary factor to be considered here is the existence of a long-felt, but unsolved need in

the art for the claimed articles and methods (*See, e.g.*, Small Declaration at ¶¶ 9-12). Umbilical cord clamps have been used to assist in delivery of newborns for decades, at least in various developed countries. A significant problem in the art is the failure, *i.e.*, non-existence, of a reliable method for visitors to the newborn, as well as the parents and hospital staff, to rapidly, accurately, and repeatedly, identify the gender of babies without removing their diaper, *e.g.*, so the proper pronoun can be used (*See, e.g.*, Small Declaration at ¶¶ 9 and 12). This problem is well known in post-natal wards. It is common knowledge, especially among parents sleep-deprived and overexcited about having a new child, tend to become indignant, irritated, annoyed, or upset when others refer to their child by the improper gender. To date, one of the best solutions for this problem involves use of blue or pink baby hats or other clothing. Unfortunately, these tend to fall off of babies, and tend to be applied improperly sometimes when exhausted health care workers re-apply the hat or other colored clothing to a baby after various treatments or clothes changes. Thus, not only do such hats or clothing not always remain with the child, but the wrong color may be applied to the child at various times causing temporary confusion (*See, e.g.*, Small Declaration at ¶ 9).

The long-felt need has not yet been satisfied by others of ordinary skill in the art to the knowledge of the Applicant, Dr. Small, who began delivering children more than 25 years ago (*See, e.g.*, Small Declaration at ¶ 10 and ¶ 12). Indeed, as far as Applicant knows, the invention of Dorsey, or the alleged combination of Merritt and Dorsey, has not been adopted by anyone else in the field of art (*Id*) even though the cited references are publicly available from the Patent Office. Thus, the allegation in the Office Action that ordinary-skilled artisans would immediately arrive at a solution is clearly incorrect because no one else has yet been adequately able to solve this problem (*See, e.g.*, Small Declaration at ¶ 12). This is evidenced by the fact that no solution has yet been made available, for example, through being published, filed as a patent application, or brought to market, to the best of Applicant's knowledge (*Id.*). Thus, the long-felt need still requires a solution, which has been elegantly and cleverly achieved by the surprising and unexpected invention presently recited in claims 17-25 (*See, e.g.*, Small Declaration at ¶¶ 10-11). The surprising and unexpected advantages of the claimed invention relative to conventional gender identification (*See, e.g.*, Specification at page 10, lines 17-28) are clear in view of the present specification. The present invention elegantly solves this problem by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later

times when clothes are worn (*See, e.g.*, Small Declaration at ¶¶ 11-12). The clamp of the invention does not typically fall off, either, and remains with the diapered-newborn baby until the cord falls off, which is generally after the baby departs from the hospital or other pre-defined area (*See, e.g.*, Small Declaration at ¶ 11). The simple fact is that millions of babies are delivered annually, and to the Applicant's knowledge no one has ever achieved such a simple, elegant solution to the problem of gender misidentification of newborn babies (*See, e.g.*, Small Declaration at ¶¶ 10-12). In fact, it should be clear common sense (in hindsight) that there is a long-felt need in the obstetric art for the improved gender-identifying clamp provided by the claimed invention. For these and other reasons, the rejection under 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn, particularly since no *prima facie* case of obviousness has been stated on the record even in view of the combination of cited references.

Accordingly, Applicant submits that all claims are again in condition for allowance in view of the MPEP and the relevant law regarding obviousness, particularly the lack of motivation to combine references and the long-felt but unsolved need in the art. Should the Examiner not agree with this position, a telephone or personal interview is requested to resolve any remaining issues and expedite allowance of this application, *e.g.*, by Examiner's Amendment.

Respectfully submitted,

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